

AMENDMENTS TO THE DRAWINGS

Please add the attached drawings, which include Figures 1-5 and which were part of original PCT application No. PCT/GB00/03141, of which the present application is a national phase application filed under Rule 371.

Attachment: Appendix A: Replacement Drawing Sheets

REMARKS

Claims 1-33, 35 and 37-52 remain pending in the application, wherein claims 1-24, 51, and 52 have been amended. No claims were added or cancelled. Reconsideration of the application is respectfully requested in view of the above amendments to the claims and the following remarks.

I. PRELIMINARY MATTERS

As requested by the Examiner, Applicant has amended the specification to refer to the claim of priority under Rule 371 as a national phase application.

Applicant is providing herewith a copy of the drawings that were part of PCT application No. PCT/GB00/03141, which is the original application filing that forms the basis of the current application. Accordingly, no new matter has been introduced by these drawings since they are part of the original filing.

The heading "Brief Description of the Drawings" was inserted in the appropriate location as requested by the Examiner.

A Supplemental Information Disclosure Statement is being submitted herewith in order to submit copies of non-U.S. patent publications and secure their consideration.

Applicant acknowledges the withdrawal of the election of species requirement and will conduct prosecution in view of that procedural change.

II. Enablement Rejection Under 35 U.S.C. § 112, First Paragraph

The Office Action rejects claims 1-33, 35 and 37-52 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The Office Action states that "[t]he claim[s] contain[] subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make the inventive glasses." Applicant regrets the fact that the drawings were separated from the application as originally filed since they, in combination with the descriptive text contained in the Examples, provide ample enablement for the claims. Applicant trusts that the submission of a replacement set of drawings as part of this amendment will allay Examiner's concerns with regards the issue of enablement. Applicant respectfully submits that the written

description of the invention, which also includes the drawings being submitted herewith, fully complies with the enablement requirements of 35 U.S.C. § 112, first paragraph.

When evaluating the quality of the disclosure contained in a patent application, an Examiner must ask "is the experimentation needed to practice the invention undue or unreasonable?" MPEP § 2164.01. A specification "enables" the claims by disclosing "how to make the claimed invention," "how to use the claimed invention," and through at least one "working example." See MPEP §§ 2164.01(b) – 2164.02. "A specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, *unless there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support.*" MPEP § 2164.04 (emphasis added).

The Office Action states that "[w]hile the relative skill of those in the art is high (PhD or chemical engineer), this is outweighed by the unpredictable nature of the art." Office Action, p. 4. In particular, the Office Action states that "specific oxides must be used to obtain the necessary solubility" and "the relative proportions of SiO₂, CaO and Na₂O must be carefully controlled to avoid producing insoluble products." Office Action, p. 5. The Office Action bases this assertion by citing two U.S. patents (U.S. Patent Nos. 6,086,374 and 5,891,233). According to U.S. Pat No. 6,086,374, widely varying amounts of SiO₂, CaO, Na₂O, and other compounds can be used to make glass compositions. See e.g. col. 5, lines 40-46. Similarly, the text accompanying Figure 5 in U.S. Pat. No. 5,891,233 cited by examiner indicates that "bioactive" glasses can be formed using wide concentration ranges of SiO₂, CaO, and Na₂O. See e.g. Figure 5 and col. 6, line 52 – col. 7, line 47. Thus, the level of unpredictability in forming bioactive glasses is not nearly as high as alleged in the Office Action according to the very patents relied on as allegedly showing a high level of unpredictability.

The specification and the drawings of the present application clearly show that the claimed compositions were made and tested. As shown in Figures 1 and 5, dozens of working compositions within the scope of the claim were prepared. Figures 1-5 and Examples 1-6 detail the preparation and testing of the inventive compositions. In particular, it was shown in both *in vitro* and *in vivo* tests that the fluoride in the inventive glasses was soluble and freely diffusible.

In addition, the Examples also discuss the installation of the inventive glasses into a dental patient's mouth either as, for example, a solid piece of glass or as a powder incorporated into a dental cement.

In addition, the Office Action states that "the specification provides no guidance whatsoever as to the particular oxides used and their specific relative proportions." Applicant respectfully submits that this is not the case. Figures 1 and 5 disclose elemental weight percentages for over 80 different glass compositions. A person having ordinary skill in the art would easily be able to determine suitable amounts of metal oxides and fluoride salts in order to yield the empirical compositions set forth in the Figures 1 and 5. For example, one of ordinary skill in the art would know that appropriate oxides and fluorides must be added to achieve the claimed elemental proportions of, for example, Na, P, Al, F, O and Mg, as exemplified in composition 14. For instance, based on what is disclosed in the specification (*see e.g.* paragraphs 10-12 and 16-17), approximately 100 grams of composition 14 (21.9 wt% Na, 20.13 wt% P, 5.27 wt% Al, 19.94 wt% F, 31.02 wt% O, and 1.75 wt% Mg) of Figure 1 can be prepared by combining 4.5 g of MgF_2 , 36.8 g of NaF, 46.2 g of P_2O_5 , 2.4 g of Na_2O , and 10.0 g of Al_2O_3 . These amounts of oxides and fluorides were easily derived from the empirical formula for composition 14 and the atomic weights for the various elements, which are found in the periodic table of the elements. Thus, not only does a composition expressed empirically in terms of weight percent of each element provide ample enabling disclosure, but it provides an excellent way to empirically claim the composition, as it most closely reflects the empirical formulations set forth in Figures 1 and 5 and described in the Examples.

As is disclosed in the specification, the constituents are combined and melted at 650° C for 45 minutes to form the glass compound. The Court of Appeals for the Federal Circuit has held that a specification is enabling when "'there [is] considerable direction and guidance' in the specification; there was 'a high level of skill in the art at the time the application was filed;' and 'all of the methods needed to practice the invention [are] well known.'" MPEP § 2164.01(a) (citing *In re Wands*, 858 F.2d 731, 740, 8 USPQ2d 1400, 1406 (Fed.Cir 1988)). The making of glass is an ancient and well-known art; the level of skill among those who possess ordinary skill in the glass making and dental arts is high; and there is "'considerable direction and guidance' in the specification" regarding the composition and preparation of the inventive glasses.

The Office Action further states that the specification does not reasonably provide enablement for the "prevention" of dental caries. Applicant respectfully disagrees. It is well-known in the dental arts that fluoride acts to prevent dental caries. *See e.g.* U.S. Patent No. 6,086,374, column 6, line 21. *See also* examples cited by Applicant in ¶ [082]. Any amount of fluoride, if it contacts teeth, can react with calcium ions present and form calcium fluoride, which is highly resistant to acidic attack, the main cause of caries.

What is more, the Office Action implies that prevention means total and complete elimination. Applicant respectfully submits that this is not how this term is commonly understood. In common parlance, when it is said that fluoride prevents dental caries it means that caries are less common among a population of individuals who receive regular fluoride exposure when compared to a population of individuals who do not. Examiner is correct when he says that "the best that can be hoped for is a minimization of [the] occurrence" of dental caries. That is precisely what "prevention" means in this instance. Applicant takes Official Notice that the American Dental Association has a published web page that asserts that fluoride can "prevent" (*i.e.*, reduce by 20 to 40 percent) tooth decay. *See* <http://www.ada.org/public/topics/fluoride/news.asp>. Accordingly, Applicant submits that the term "prevent", as used in the claims, is used in accordance with the standard and well-accepted understanding of this term as used by the American Dental Association (*i.e.*, "prevention" does mean complete and absolute "elimination" in the context of the treatment of caries but a statistical reduction).

In view of the foregoing, Applicant submits that the specification, particularly when read in light of the previously missing drawings, is fully enabling with respect to how to manufacture and use glass compositions that are able to release fluoride when exposed to saliva in a person's mouth. Moreover, such compositions release fluoride, which is well understood by those of skill in the art to treat and "prevent" caries.

Applicant notes that the independent claims have been amended in order to limit the claimed compositions to those glass compositions that are able to release water soluble fluoride ions over time when exposed to saliva in a person's mouth. That is the essence of the invention as described throughout the application (*e.g.*, paragraph [053]). Not all glass compositions are able to release water-soluble fluoride ions. The claims as now amended expressly exclude such compositions, which would not serve the purpose of treating or preventing caries.

II. REJECTION OF "USE" CLAIMS UNDER 35 U.S.C. §§ 101 and 112

In response to Examiner's objection to the term "use," claims 1-17, 21, and 22 have been amended to simply claim a glass composition having the claimed characteristics.

III. PROVISIONAL OBVIOUSNESS-TYPE DOUBLE PATENTING REJECTION

The Office Action provisionally rejects claims 1-33, 35 and 37-52 on the grounds of nonstatutory double patenting relative to claims 1-25 of copending U.S. application Serial No. 10/276,218. Because the claims are only provisionally rejected, Applicant respectfully declines to respond to this rejection at this time. Applicant agrees, however, to file an appropriate terminal disclaimer upon the allowance of this application or copending application Serial No. 10/276,218.

IV. PATENTABILITY OF THE CLAIMS OVER THE ART OF RECORD

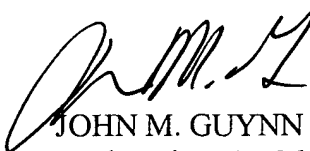
The Office Action acknowledges that the claims as previously presented define compositions and methods that are neither taught nor suggested in any of the art cited in the International Search Report.

V. CONCLUSION

In view of the foregoing, Applicant submits that the application is in allowable form. In the event that the Examiner finds any remaining impediment to a prompt allowance of this application, which may be clarified through a telephone interview or that may be overcome by examiner amendment, the Examiner is requested to contact the undersigned attorney.

Dated this 27th day of June 2006.

Respectfully submitted,



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